Medical Policy
Antigen Leukocyte Antibody Test

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Policy Number: 673
BCBSA Reference Number: 2.01.93
NCD/LCD: NA

Related Policies
- Diagnosis and Management of Idiopathic Environmental Intolerance or Clinical Ecology, #264

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity
Medicare HMO BlueSM and Medicare PPO BlueSM Members

The Antigen Leukocyte Antibody Test (ALCAT) is NOT MEDICALLY NECESSARY for all indications.

Prior Authorization Information
Pre-service approval is required for all inpatient services for all products.
See below for situations where prior authorization may be required or may not be required for outpatient services.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th>Outpatient</th>
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<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>This is not a covered service.</td>
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<td>Commercial PPO and Indemnity</td>
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<td>Medicare HMO BlueSM</td>
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<td>Medicare PPO BlueSM</td>
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CPT Codes / HCPCS Codes / ICD Codes
Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.
CPT Codes
There are no specific CPT codes for this service.

Description
The Antigen Leukocyte Antibody Test (ALCAT) is intended to diagnose intolerance to foods and other environmental agents. It is a blood test that assesses the response of leukocytes and platelets to a panel of foods and/or other environmental agents, by measuring the change in size and number of cells following exposure to a specific agent.

Background
Environmental illness refers to a physiologic reaction that is triggered by an exogenous agent, which can be ingested, inhaled, or exposed through direct contact with skin. The physiologic reaction can be an immunologic response or a nonimmunologic response. An adverse physiologic reaction to exogenous antigens has been proposed to play a causative role in a wide variety of illnesses, including allergies, gastrointestinal (GI) tract disorders such as irritable bowel syndrome, eczema, chronic fatigue, and migraine headache. Food allergy is the most well-defined type of environmental illness and is estimated to affect 8% of children. In most cases, true food allergy is characterized by a classic immunologic response, ie, an IgE mediated reaction in response to a specific protein allergen. Reactions can range from mild symptoms to life-threatening anaphylaxis. Current guidelines for the diagnosis and management of food allergies have been developed by the National Institute of Allergy and Infectious Diseases. Food intolerance is a broader term that overlaps with food allergy but is less well-defined. Food intolerance refers to physiologic reactions that are triggered by a particular food, but which are not immune-mediated. It is hypothesized that physiologic reactions to food may manifest as a range of nonspecific symptoms, such as GI complaints, headache, fatigue, and musculoskeletal complaints and that these symptoms may become chronic with repeated exposure. An example of food intolerance, distinguished from a true food allergy, is lactose intolerance, in which dairy products incite nonimmunologic reaction that can lead to a constellation of GI symptoms.

Treatment of environmental illness primarily involves avoidance of the inciting agent. Acute allergic reactions are treated in the same way as other types of allergies with antihistamines, steroids, and supportive measures. In cases of severe allergy where an agent cannot be definitively avoided, patients can carry and self-administer auto-injectable epinephrine when needed. Prophylactic antihistamines can also be used to prevent or lessen reactions. Allergy immunotherapy may be appropriate for selected allergens.

For patients with food intolerance that is not allergic in nature, identification of the inciting agent(s) can be difficult because the symptoms are chronic in nature. Use of an elimination diet is considered the best way to identify intolerant agents. In an elimination diet, 1 specific food or food group is eliminated from the diet for a specified period of time and symptoms observed. Following the elimination period, a rechallenge can be performed to ascertain whether symptoms return. Elimination diets often need to be done sequentially with a large number of items, so that the process can be lengthy and cumbersome.

ALCAT test. The ALCAT test is intended to identify foods and other environmental agents for which an individual may have intolerance. It is not intended to diagnose food allergy. The test is based on the theory that a substantial increase in leukocyte size and number is characteristic of an intolerant response. Identifying the specific inciting agent facilitates avoidance of that agent, which may lead to a reduction in symptoms. In this regard, ALCAT testing has been used as a tool for developing an elimination diet that is targeted to the most likely offending agents.

The test is performed by taking a sample of blood, which is first treated to remove the red blood cells and tested to determine the baseline number and size of leukocytes and platelets. Measurement of size and count of cells is performed by the Coulter technique, which is a standard technique in clinical hematology.
Next, a small quantity of blood is incubated with multiple agents. Following exposures, change in the number and size of cells is determined for each exposure. A 10% increase in the size of leukocytes is considered characteristic of a response to an intolerant agent.

The ALCAT website (Cell Sciences Systems, Deerfield Beach, FL) lists 11 separate panels consisting of various combinations of foods, herbs, food additives/coloring, and environmental chemicals. The total number of agents tested in these panels range from 70-320.4

Summary
The Antigen Leukocyte Antibody Test (ALCAT) is a blood test that is intended to diagnose intolerance to foods and other environmental agents. There is a lack of published research on the diagnostic accuracy of the test; therefore it is not possible to determine the sensitivity, specificity, and/or predictive value of the test compared with alternatives. A few low-quality studies report improvement in outcomes following use of the ALCAT test, but it is not possible to determine whether these changes occur as a result of test itself, versus bias, variation in the natural history of the condition, and/or the placebo effect. Guidelines for the diagnosis of food allergy from the National Institute of Allergy and Infectious Disease (NIAID) do not discuss use of the ALCAT test. Due to the limitations of the evidence base, and lack of acceptance of the test as a component of standard care by experts in this area, the ALCAT test is considered not medically necessary for all indications.

Policy History

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Information Pertaining to All Blue Cross Blue Shield Medical Policies
Click on any of the following terms to access the relevant information:
- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
- Medical Technology Assessment Guidelines

References
7. Kaats GR PD, Parker LK. The Short Term Efficacy of the ALCAT Test of Food Sensitivities to Facilitate Changes in Body Composition and Self-reported Disease Symptoms: A Randomized Controlled Study. The Bariatrician 1996; Spring:18-23.